REMARKS

The Office Action has rejected Claims 1-22 and 25-40 under 35 U.S.C. §102(b) or in the alternative under 35 U.S.C §103(a) as defining subject matter which is allegedly anticipated or rendered obvious by the teachings in WO 92/16545, of which Heikkila, et al. are the inventors ("Heikkila, et al.").

Applicants have added and amended claims, which when considered with the comments hereinbelow, have placed the application in condition for allowance. Favorable action is respectfully requested.

Before addressing the merits of the rejections, applicants point out that Claim 14 has been amended to correct an obvious grammatical error. In addition, Claims 41-52 have been added to the specification. Support thereof is found in the instant specification. Support for Claims 41 and 42 is found on Page 8, line 23 to Page 9, line 4 (the last paragraph on Page 8 and bridging Page 9 and the first paragraph on Page 9) and original Claim 23 of the instant specification. The subject matter in Claims 43-46 is supported by original Claim 3 and Page 4, lines 10-14 of the instant specification. Support for Claim 47 is found on Page 4, line 14 of the instant specification, while support for Claim 48 is found on Page 3, line 25 to Page 4, line 3 and Page 4, lines 23-29 of the instant specification. Support for Claims 49-52 is found on Page 3, line 25 to Page 4, line 3 and Page 7, Lines 21-25 of the instant specification.

No new matter has been added to the application.

The present invention is directed to β-lactitol and anhydrous β-lactitol and the use thereof and the process for making the β-lactitol.

Pursuant to the rejection of Claims 1-22 and 25-40 under 35 U.S.C. §102 or in the alternative under 35 U.S.C. §103, the Office Action cites Heikkila, et al.

Heikkila, et al. disclose lactitol α crystals; it does not teach, disclose any β-lactitols, as presently claimed. As shown in the present application, the α form is quite different from the β-form. Attention is directed to Page 8 of the instant specification, which compares the α and β lactitols. As clearly shown by the data in Table 1, the α and β forms have different crystal forms, the α-lactitol form being monoclinic, while the β form is orthorhombic. Moreover, they have different spatial groups, the α has the spatial group $P2_1$ while the β lactitol having the spatial group $P2_12_12_1$. Moreover, the β-lactitol has different unit cell parameters than the α-lactitol. As described in the underlying application, the unit cell parameters of the β crystal form of lactitol are a is about 9.69Å, b is about 11.1 Å and c is about 14.0 Å, while the parameters for the α-crystal is a = 7.614Å, b = 10.757 and c = 9.370 Å, as disclosed in Heikkila, et al. on Page 4, lines 3-7 thereof. The characteristics identifying the β-lactitol are recited in Claims 1 and 6; as clearly seen by the data in Heikkila, et al. these are not characteristics of the α-lactitol.

Moreover, these characteristics recited therein are not applicable to any other lactitol that is known. Thus, Claims 1, 6, 33 and 34 are directed to subject matter not contemplated by Heikkila, et al. Moreover, as shown by the underlying specification, the β crystals have different properties than the α lactitols. For example, the β crystals are harder than the α crystals. Further, they have different melting enthalpies with the α form being 149 J/g, while the β form is 166-169 J/g. Moreover, as indicated in the specification, the α and β forms can be easily distinguished in the X-ray powder diffraction as a result of the different structures, clearly revealing that they are different. Furthermore, these different crystal forms translate into different characteristics, e.g. different morphology, heats of fusion, solubility, hygroscopicity and hardness. These different physical properties manifest themselves into different characteristics

exhibited by the β-lactitol crystals relative to the α-crystals. For instance, the β lactitol crystals are very stable and they are harder than the α lactitol crystals as described on Page 8 of the instant specification. This gives technical advantages, e.g. in foodstuffs and special tooth pastes. Both anhydrous lactitols are non-hygroscopic, but the β lactitol absorbs water even more slowly than does the α lactitol. This makes the β lactitol even more stable than the α lactitol at storage in moist and warm conditions, thereby making products containing the β lactitol more stable than similar products containing α-lactitols in lieu of the β-lactitol. The β lactitol has a lower solubility at high temperatures than the α lactitol. This affects the way the two lactitol forms dissolve in liquids during use and processing. The melting enthalpy of the β lactitol is higher than that of the α lactitol, which means that it needs more heat to melt or, in other words, it remains a solid for a longer time without melting. Thus, the composition of matter containing β lactitols have unexpected advantages over the corresponding composition of matter containing α lactitol.

Additionally, as will be shown below in connection with a discussion on the methods, the β lactitol crystals cannot be formed under the conditions as described in Heikkila, et al. which favour the production of the α lactitol crystals. Thus, it is indeed highly unlikely that such β lactitol crystals have ever been produced even by mistake by the processes of Heikkila, et al. Moreover, when the α lactitol is subjected to X-ray diffraction analysis, no β-lactitol form has even been detected.

Thus, since the prior art reference is limited to lactitol in the α-form, and since the β-lactitol crystals cannot be made under the conditions favoring the production of α-lactitol crystals, Heikkila, et al. cannot teach, disclose or suggest the claimed subject matter of the present application.

Moreover, the prior art process of Heikkila, et al. is non-enabling as to the production of the β lactitol and as such cannot destroy the novelty of the β lactitol, as claimed. A β lactitol formed by the prior art process is non-existent and hence cannot take away the patentablitliy of the β lactitol.

Thus the β lactitol has properties different from those of the α lactitol crystals produced in the prior art reference. These different properties are unexpected and have an influence on the technical utility and industrial applicability of the new lactitol form. Hence, it is respectfully submitted that the β lactitol shows an inventive step over the prior art.

Moreover, the processes of making the β lactitol are different and patentable over that in the prior art. As described on Page 5 of the present application, the processes of making the β lactitols are different from those in making the α lactitols. In one embodiment, as recited in Claim 10, the β lactitols are formed by conditioning the α lactitol solution. Since the β lactitols are made from the α-lactitols, and since Heikkila, et al. is limited to making α-lactitols, the process of making β-lactitols is not taught, disclosed or suggested therein. Thus, the process claimed for making β-lactitols is patentable over the teachings of α-lactitols.

For example, the conditioning step, as recited in the process of claim 10 is a very specific feature which provides the novel β lactitol. The reason for this will be explained below with reference to some theoretical considerations of crystal formation.

The β lactitols will not crystallize as easily as the α lactitol in aqueous solutions. In actual fact it has been shown that the β lactitol will not crystallize in solutions where α lactitol crystals are forming and/or growing. The β lactitol is very much slower at crystallizing and its nucleation mechanism is prohibited as long as α lactitol crystals are growing. This means that as long as the supersaturation of a crystallizing lactitol solution is maintained above the solubility

line of the α lactitol, then α lactitol will crystallize and β lactitol cannot crystallize. In Heikkila, et al. the processes described therein have the supersaturation of the α-lactitol solution above the solubilizing line of the β-lactitol. Thus, the process for making α lactitol, as described in Heikkila, et al. cannot make β lactitols, as claimed.

A person skilled in the art is well aware of the fact that during a normal cooling crystallization, the concentration of lactitol in the solution gradually diminishes as dissolved lactitol in the solution transfers from the liquid phase into the solid α crystalline phase. At the same time and in accord with the crystallization, the temperature is lowered (cooled) so that the supersaturation is kept above the solubility line of the desired α lactitol. If the crystallizer would allow the supersaturation to fall below the α lactitol saturation level (i.e. below the α lactitol solubility line) then the already crystallized α lactitol would start to dissolve. Thus, the crystallizer will keep the saturation level at a high enough level so as to have a driving force (supersaturation) creating α lactitol crystals and not a driving force (undersaturation) dissolving the α crystals.

It is only when the saturation of the solution drops to or below the solubility line of the α lactitol that the β lactitol crystals start to be generated and can grow. This does not happen during the crystallization procedures aimed at producing the α lactitol as described in Heikkila, et al.

If the α lactitol crystals are recovered from the solution, no β lactitol is formed, since the transformation from α to β has not been observed to take place in the dry state. If the temperature of the solution is allowed to fall below about 69°C, lactitol monohydrate will start to form and no β lactitol will form.

Thus, for example, when the procedure of claim 10 is operated, the cooling

crystallization is first operated normally to provide the first (α lactitol) crystal yield. When the solution has been cooled down to the desired temperature the cooling stops and then the conditioning starts. As described in the specification the conditioning keeps the solution at a certain temperature (see also the examples which define constant conditioning temperatures of about 85 or 70 °C, respectively). During the conditioning there is thus no cooling any longer. A review of Heikkila, et al. clearly reveals that the conditioning step is not described therein.

When the cooling stops, α lactitol crystals will continue growing until no supersaturation in regard to α lactitol remains. At this point, there is no driving force left to produce α lactitol. Thus, it becomes energetically possible for β lactitol crystals to grow. β-lactitol has a lower solubility than α lactitol and thus, the solution is still supersaturated for β lactitol although it is no longer supersaturated for α lactitol. It seems that the β lactitol crystal formation mechanism is no longer prohibited when α lactitol cannot crystallize.

During the 'conditioning' defined in the present invention, the α lactitol crystals are retained in the solution without any further cooling. When the supersaturation for α lactitol crystals has been "consumed", β lactitol crystals can start to grow, and slowly, the α lactitol transforms in the solution into β lactitol at the conditioning (non-cooling) temperature. The same phenomenon is applicable to the processes described in Claim 14 and 15 and those dependent thereon. Since the conditioning steps are not disclosed in the Heikkila, et al. reference, it does not teach, disclose or suggest the prepartion of β-lactitols, as claimed.

Thus, it is clearly seen that the processes described in Heikkila, et al. do not teach, disclose, suggest or make obvious the processes of claims 10 to 16 which provide β lactitol crystals.

The process of claim 17 is "slow" compared to the prior art processes. According

to the specification on page 6, bottom paragraph, the cooling may take two days or more. Since the prior art does not maintain a crystal mass in the mother liquor for any prolonged period of time at elevated temperatures, the prior art process as described in Heikkila, et al. could not make β-lactitol. A person skilled in the art will understand that in such a very slow cooling, the α lactitol formation consumes all of the α lactitol supersaturation in the solution and when this happens, then β lactitol crystals can be formed and can grow. Moreover, the formation of β lactitol crystals is greatly enhanced by the addition of seed crystals into the solution and if that is done, as in claim 18, then the slow cooling is more certain to provide β lactitol. This seeding of β lactitols was not described or suggested in Heikkila, et al. The β lactitol is also enhanced by certain accelerators such as lactulitol as defined in claim 20, which process is not taught or disclosed or suggested in the prior art.

Thus the processes of the prior art do not disclose the processes of the present application nor do they make the obtaining of the new and totally unexpected β lactitol obvious.

Moreover, since the β lactitol as such is new and inventive, also its uses and compositions of matter containing same are new. Further, the stability, hardness, solubility and improved non-hygroscopicity of the β lactitol relative to the α lactitol are totally unexpected and this makes the compositions of matter and the use thereof in various applications inventive over the prior art use of α lactitol.

Furthermore, even if some α-lactitol is present with the β-lactitols, the prior art does not teach, disclose or suggest any composition containing any β-lactitols for example, both α lactitols and β lactitols.

Since the prior art does not teach, disclose or suggest β lactitols or the unexpected advantages of β lactitols relative to α lactitols or the processes of making β-lactitols, the

rejection of the claims under 35 U.S.C. §103 is obviated. Withdrawal thereof is respectfully requested.

Thus, in view of the remarks herein, it is respectfully submitted that the present case is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

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